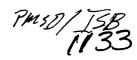
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

SEP 1 9 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT:

2724-321. Phosmet. Residue Study Protocols.

No Accession Number. RCB No 1358.

FROM:

Leung Cheng, Chemist 🔍

Residue Chemistry Branch

Hazard Evaluation Division (TS-769C)

TO:

George LaRocca, PM 15

Fungicide-Insecticide Branch Registration Division (TS-767C)

THRU:

Edward Zager, Section Head, SRS II

Residue Chemistry Branch

Hazard Evaluation Division (TS-769C)

Zoecon has submitted two residue study protocols for dip (dermal) use of phosmet [N-(mercaptomethyl)phthalimide S-(0,0-dimethylphosphorodithioate)] on beef cattle.

In 1984, the registrant requested higher dip treatment rates (0.3% phosmet concentration maximum, 1:200 RF-224:water dilution). RCB recommended against these new dip treatment concentrations initially for the lack of appropriate residue data and the impracticality of the 21-day PSI (L. Cheng's review dated 1/8/85), but subsequently recommended for a restricted use (for feedlot use only) and conditional approval (additional residue data in 12 months, L. Cheng's review dated 2/25/86).

The product chemistry and residue chemistry chapters of the Registration Standard were issued on April 15, 1986.

The first protocol is a pilot residue study. One steer and 2 heifers are to be totally immersed once in a dip vat solution of 0.3% phosmet concentration (1% use rate). Samples of blood and subcutaneous fat (near the base of the tail) will be collected before sacrifice. Samples of muscle, kidneys, liver, omental fat, perirenal fat, subcutaneous fat and blood will be analyzed in triplicate for residues of phosmet and its oxygen analog. A validated method with a combined sensitivity of 0.1 ppm or lower is to be used. The samples will be stored in dry ice if not analyzed within two hours of sampling. Samples will be retained frozen for up to six months.

The second protocol is titled "A Modified Residue Study to Assist in Establishing a Withdrawal Period for Zoecon RF-224 Phosmet Flowable Dip in Beef Cattle". Four groups each consisting of one steer and one heifer are to be totally immersed in a dip vat solution of 0.3% phosmet concentration twice, 7 days apart. Vat concentration will be analyzed prior to dip treatment. Cattle consisting of 2 steers and 2 heifers will serve as controls and will not be sham dipped but will receive the same ration as treated animals throughout the testing and sampling periods. Samples of subcutaneous fat near the base of the tail will be collected (biopsy) at 1, 3, 10, and 17 days after the second treatment. Cattle (a steer and a heifer) will be sacrificed at 3, 7, 14, and 21 days after the second dose. Control animals will not be biopsied and will be sacrificed on day 7 and day 21. Samples of muscle, kidneys, liver, omental fat, perirenal fat. subcutaneous fat and blood will be collected upon sacrifice and analyzed in triplicate for phosmet and its oxygen analog. previously validated residue method with a combined sensitivity of at least 0.1 ppm for both compounds is to be used. Samples will be frozen only if not analyzed within 2 hours of collection and retained for 6 months.

We have the following comments.

- 1. The label allows repeated dip treatments "as necessary". The proposed frequency of two dip treatments is not adequate.
- 2. The amount of time an animal stays in the dip vat is not specified on the label. This information is needed and the tests should be conducted accordingly.
- 3. We recommend at least 3 animals be used in the first two groups of cattle in which the animals are to be sacrificed at 3 and 7 days after the last dose, respectively.
- 4. The controls should be housed separately from the treated animals.
- 5. The residue method should have a sensitivity of at least $0.05\ ppm$ for phosmet and its oxygen analog.
- 6. Data on storage stability and recovery should accompany the residue data.
- 7. According to the Registration Standard, additional animal metabolism studies are necessary. We recommend the tissue samples be retained until the data gaps on the animal metabolism have been fulfilled.
- 8. Representative chromatograms or curves on controls, treated and fortified samples of tissues should be submitted.

Recommendation

We recommend these comments be sent to Zoecon.

cc: Circ, SF, RF, Amended Use F, Cheng, PMSD/ISB
RDI:EZager:9/18/86
TS-769:RCB:LCheng:CM#2:Rm810:9/18/86:557-7324:6